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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,412	12/06/2000	Howard Bernstein	ACU 105 DIV(2)	9414

23579 7590 12/24/2002

PATREA L. PABST  
HOLLAND & KNIGHT LLP  
SUITE 2000, ONE ATLANTIC CENTER  
1201 WEST PEACHTREE STREET, N.E.  
ATLANTA, GA 30309-3400

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/24/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.



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**MAILED**  
**DEC 24 2002**  
**GROUP 2900**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 15

Application Number: 09/731,412  
Filing Date: December 06, 2000  
Appellant(s): BERNSTEIN ET AL.

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Patrea L. Pabst  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 9/16/02.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

Art Unit: 1617

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the issues in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

Appellant's brief includes a statement that claims 20-24, 27-32 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

**(8) *Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) *Prior Art of Record***

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

**(10) *Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

5, 942, 253

GOMBOTZ

8-1999

Claims 20-24, 27-32 are rejected under 35 U.S.C. 102. This rejection is set forth in prior Office Action, Paper No. (e).

**(11) Response to Argument**

Applicants argue that the water-soluble pore formers of GOMBOTZ would not inherently be removed with the (organic) solvent. However, applicants do not claim removal of pore-formers with the solvent for the polymer. They claim removal of the pore-former. It is argued that the washing step with water will remove the water-soluble pore formers. Applicants argue, but do not claim a volatile pore-forming agent.

Applicants suggest that the pore-formers are not added to the polymer. However, column 9 lines 34-36 disclose that excipients, including pore formers, can be mixed with the particulate active agent GM-CSF as another particulate<sup>1)</sup>, both of which can be added to the polymer solution (column 8 lines 9-10).

Applicants argue that the ratios of GOMBOTZ at column 10 lines 9-8 are not a ratio of hydrophobic compound to polymer in claims 21-22. Applicants intend claims 22-23. However, 4:1 lipid to protein, given that the protein, <sup>the</sup> ~~are~~ active GM-CSF<sub>5</sub> can be as high as 10% of the polymer (column 9 lines 18-20), indicates that the lipid can be up to 40% of the polymer.

Applicants argue that GOMBOTZ doesn't teach micro particles of active. However, GOMBOTZ teaches fine particles of the active GM-CSF (column 8 lines 9-10), within the polymeric micro particle vehicle, suggesting the GM-CSF is a smaller micro particulate. Claim II refers specifically to micro particles comprising GM-SCF dispersed in polymeric micro particles.

Art Unit: 1617

Applicants argue that GOMBOTZ teaches hydrophobic compounds as stabilizers for the active GM-SCF rather than modifiers for controlled release. However, applicants claim a method of administering rather than a method for modulating controlled release. That is, the modification of controlled release is claimed, as a property, which, it is argued, is inherent in the GOMBOTZ method of administration. Applicants' argument of surprising results is not relevant to a 102 rejection. Further, such results are not characterized as surprising in the specification. Indeed, it would not be surprising for a hydrophobic compound to increase release of a hydrophobic drug by providing a pathway out of the polymer matrix.

Applicants argue that GOMBOTZ does not teach rectal, vaginal, or pulmonary administration. However, applicants do not claim such administrations. They instead claim a formulation intended for such a use.

Art Unit: 1617


For the above reasons, it is believed that the rejections should be sustained.


Respectfully submitted,

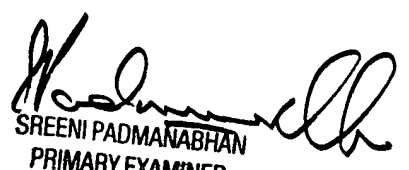
Webman/T.G. D.  
December 19, 2002

Conferees

PATREA L. PABST  
HOLLAND & KNIGHT LLP  
SUITE 2000, ONE ATLANTIC CENTER  
1201 WEST PEACHTREE STREET, N.E.  
ATLANTA, GA 30309-3400

  
THEODORE J. CRIARES  
PRIMARY EXAMINER  
GROUP 1200

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

(SPE) 12/23/02